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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CINDY SUNSERI,

Plaintiff,

v.

JOHNSON AND JOHNSON, ETHICON, INC., ETHICON US, LLC, and ETHICON ENDO-SURGERY, INC.,

Defendants.

Case No.

COMPLAINT FOR DAMAGES; DEMAND FOR JURY TRIAL

1. Strict Products Liability -Manufacturing Defect
2. Strict Products Liability – Failure to Warn
3. Strict Products Liability – Design Defect
4. Breach of Implied Warranty
5. Breach of Express Warranty
6. Negligence
7. Violation of Business &Profession Code § 17200
8. Violation of Business & Profession Code § 17500
9. Violation of Civil Code § 1750

Plaintiff, CINDY SUNSERI ("Plaintiff"), by and through her undersigned counsel and for causes of action against Defendants JOHNSON AND JOHNSON, ETHICON, INC., ETHICON US, LLC, and ETHICON ENDO-SURGERY, INC., alleges and states as follows:

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PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, CINDY SUNSERI, was, and at all times relevant times, a citizen of the State of California, and a resident of Santa Clara County, California.

2. Defendant JOHNSON & JOHNSON ("J&J") is a foreign for-profit Corporation with its principal place of business in New Brunswick, New Jersey, and is a citizen of the State of New Jersey. All acts and omissions of J&J as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership. J&J is a manufacturer of surgery products, consumer products related to healthcare, health, beauty products, and medical devices, and is a citizen of the State of New Jersey, with its corporate headquarters located in New Brunswick, New Jersey.

3. Defendant Ethicon, Inc. ("Ethicon") is a foreign for-profit Corporation with its principal place of business in Sommerville, New Jersey, and is a citizen of the State of New Jersey. It is a subsidiary of Johnson & Johnson, incorporated under the Johnson & Johnson umbrella in 1949 to expand and diversify the Johnson & Johnson product line. All acts and omissions of Ethicon as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership. Ethicon is a manufacturer of surgery products and surgical sutures and is a citizen of the State of New Jersey, with its secondary corporate headquarters located in Cincinnati, Ohio.

4. Defendant Ethicon US, LLC ("Ethicon US") is a foreign for-profit Corporation with its principal place of business in Cincinnati, Ohio, and is a citizen of the State of Ohio. It is a subsidiary of Johnson & Johnson, incorporated under the Johnson & Johnson umbrella in 1949 to expand and diversify the Johnson & Johnson product line. All acts and omissions of Ethicon US as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership. Ethicon US is a manufacturer of surgery products and is a citizen of the State of Ohio, with its secondary corporate headquarters located in New Jersey.

5. Defendant Ethicon Endo-Surgery, Inc. ("Ethicon Endo") is a foreign for-profit Corporation with its principal place of business in Cincinnati, Ohio, and is a citizen of the State of

Ohio. It is a subsidiary of Johnson & Johnson, incorporated under the Johnson & Johnson umbrella in 1949 to expand and diversify the extensive Johnson & Johnson product line. All acts and omissions of Ethicon Endo as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership. Ethicon Endo is a manufacturer of surgery products and is a citizen of the State of Ohio, with its secondary corporate headquarters located in New Jersey.

6. "J&J", "Ethicon", "Ethicon US", and "Ethicon Endo" are collectively hereinafter referred to as the "J&J Defendants" or "Defendants."

7. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. § 1332(a)(1) because the amount in controversy exceeds seventy-five thousand dollars ($75,000.00) and there is complete diversity of citizenship between the parties.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the acts and/or omissions giving rise to these claims occurred within this District and Defendants are engaged in significant business activities within this District.

THE J&J DEFENDANTS

9. At all times material hereto, the J&J Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the pelvic mesh products at issue in this matter. By said activities, J&J Defendants' Prolene mesh products were placed into the stream of commerce throughout the United States, including the State of California.

10. At all times material to this action. The J&J Defendants designed, patented, manufactured, labeled, marketed, sold and distributed a line of Prolene mesh products. The products by the J&J Defendants were designed primarily for the purposes of treating hernias and pelvic organ prolapse. The J&J Defendants' product at issue in this case were cleared for sale in the U.S. after the J&J Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety of efficacy.

11. The J&J Defendants conducted substantial business in the State of California and in

this District, distributes hernia mesh products in this District, receives substantial compensation and profits from sales of Prolene mesh products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to in personam jurisdiction in this District.

12. The J&J Defendants conducted business in the State of California through sales representatives conducting business in the State of California and because the J&J Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or selling, either directly or indirectly, and/or through third parties or related entities, hernia mesh products; thus, there exists a sufficient nexus between each J&J Defendants forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in California.

13. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has in personam jurisdiction over the J&J Defendants, because they are present in the State of California such that requiring an appearance does not offend traditional notices of fair play and substantial justice.

14. The J&J Defendants are subject to personal jurisdiction in this district as they systematically and continually conduct business in this district, and conduct business throughout the United States, including California.

FACTUAL BACKGROUND

15. Plaintiff, Cindy Sunseri, was surgically treated for an umbilical hernia repair at Santa Clara Valley Medical Center in San Jose, California on 09/13/2010. During the surgery, an Ethicon Prolene Hernia Mesh System ("PHSM") was implanted in her abdominal area.

16. Subsequently, at a post-operative checkup her treating physician, Dr. Cahill noted that Ms. Sunseri had an abscess and cellulitis surrounding her previous repair. An Incision and Drainage ("I&D") surgery was performed to correct the infection around the surgical site, which was caused by the failure of the PHMS.

17. On 08/18/2015, Ms. Sunseri suffered another abscess and cellulitis surrounding her previous repair that required treatment. An I&D surgery was performed to correct the infection around the surgical site.

18. Soon afterwards Plaintiff suffered another infection, later determined to be due to an additional piece of her failed PHSM and had to undergo another procedure in order to remove the latter piece.

19. On 10/16/2015, Ms. Sunseri had a CT scan performed which demonstrated that she had an adhesion of the small bowel to a piece of the failed PHMS. This complication, further resulting from the failure of the PHMS, required another I&D surgery.

20. Because of these surgeries and procedures to correct the complications that resulted from the failure of the Ethicon PHMS, Ms. Sunseri now has ongoing complications that have had a severe negative impact on her quality of life. Due to the repeated surgeries, the umbilical hernia itself has not been able to heal, so the abdominal surgical site remains open, indefinitely exposing the interior of her abdominal cavity. This necessarily places her at significant risk for life threatening infection.

21. Her open surgical wound requires constant maintenance, including daily wound dressing changes at home, as well as weekly wound dressing changes at a specialized wound care clinic. These involve painful packing of sterile gauze into the wound itself. These complications place Ms. Sunseri in a constant state of excruciating abdominal pain.

22. The failure of the Ethicon PHMS was the source of the complications and pain in and around Ms. Sunseri's abdominal area. Ms. Sunseri is at risk for future recurrent infections and complications caused by remnant pieces of the failed Ethicon PHMS.

23. At all times relevant to Plaintiff's Complaint, the Ethicon Defendants, as subsidiaries of J&J manufactured, promoted, distributed and sold for profit a product entitled The Johnson & Johnson/Ethicon Prolene Mesh ("J&J Prolene Mesh" or the "Product"). The J&J Defendants promoted, distributed, and sold the J&J Prolene Mesh, as a product to repair hernia surgeries in the population, as well as to repair pelvic organ prolapse and stress urinary incontinence.

24. J&J is an American multinational medical device, pharmaceutical and consumer packaged goods manufacturer founded in 1886. The corporation includes some 250 subsidiary companies with operations in 60 countries and products sold in over 175 countries. J&J had worldwide sales of $70.1 billion in calendar year 2015. The company's business is divided into three

major segments: (1) Pharmaceuticals, (2) Medical Devices, and (3) Consumer Products.

25. Ethicon has manufactured surgical sutures and wound closure devices since 1887. After World War II, Ethicon's market share in surgical sutures rose from 15% to 70% worldwide. In the United States, the market share is approximately 80%. Ethicon conducts business in 52 countries. In 1992, Ethicon was restructured, and became a separate corporate entity. During the 1990s, Ethicon diversified into new and advanced products and technologies and formed four different companies under the Ethicon umbrella, each of which specialize in different products. In November 2008, the wound management business was sold to One Equity Partners and became Systagenix Wound Management Limited.

26. Ethicon describes the product as follows, "For Open Ventral and inguinal hernia repair. Potential for improved patient comfort and healing." The Company's website continues: Nonabsorbable, synthetic mesh for the repair of abdominal wall fascial defects. Unique design results in a mesh that is approximately 50% more flexible than standard PROLENE Polypropylene Mesh.

27. Ethicon Prolene Mesh is a synthetic monofilament suture used to treat hernias, pelvic organ prolapse (POP), and stress urinary incontinence (SUI). It is made of polypropylene (PP), a petroleum-based plastic. It is composed of isotactic crystalline stereoisomer of polypropylene. The name Prolene is a trademark of Ethicon and is produced in Cornelia, Georgia.

28. Unfortunately, despite originally being considered a revolutionary breakthrough in medical device technology, Prolene Mesh has recently been associated with complications including mesh erosion, infections, pain, dyspareunia, organ perforation, and the recurrence of urinary problems. Prolene Mesh is also extremely difficult to remove once it has been implanted, meaning many may lose organs or must have severely invasive surgeries for mesh removal. Even then, because the mesh incorporates itself into tissue, complete removal of mesh remnants is difficult, if not impossible. Ethicon, as a subsidiary of J&J, continued to advertise to the medical community and public that the prolene mesh is a Nonabsorbable mesh that is flexible ideal for inguinal hernia surgery repair, such as that suffered by the Plaintiff.

29. The Ethicon Prolene mesh was approved by the FDA through a backdoor called 501(k). It means the product was not tested by the FDA as other new products would be because it is

"substantially similar" to other surgical meshes such as Ethicon's UltraPro, Proceed, and Physiomesh. The Prolene mesh recalls have found that they are prone to break, leading to bowel perforations and chronic intestinal fistulae. Several lawsuits against Ethicon have found that the mesh disintegrate into victims' bodies, leading to infections and other serious complications. The FDA ordered Ethicon to cease production until extensive testing and research was conducted on some of Ethicon's product line, including its vaginal mesh devices, or its Prolift device. In June 2012, following the FDA's order for additional testing, Johnson & Johnson permanently removed all Prolift products from the market.

30. In fact, Ethicon has issued statements for the recalls of their hernia products, stating: "The recurrence/reoperation rates (respectively) after laparoscopic hernia repair using Ethicon Physiomesh Composite Mesh were higher than the average rates of the comparator set of meshes among patients in these registries."

31. The J&J Defendants currently have thousands of lawsuits pending against them for the mesh products lines, including the Prolene Mesh inserted into the Plaintiff, Cindy Sunseri. On July 13, 2011, the FDA issued a Safety Communication update citing the common side effects of using surgical mesh in the pelvic region: (1) mesh erosion, (2) pain, (3) infection, (4) urinary problems, (5) bleeding, and (6) organ perforation. There were also reports of organ prolapse, neuro-muscular problems, severe pain, mental anguish, and emotional trauma. Many of the medical device reports cited the need for additional intervention, including medical or surgical treatment and hospitalization. All the Johnson & Johnson Pelvic Floor Repair System products have been implicated, including the Prolift, Prolene, Gynecare TVT Sling, and Gynecare TVT-O.

32. The FDA's literature review has found that erosion of mesh through tissue is the most common and consistently reported mesh-related complication from surgeries using mesh. The scientific evidence adduced thus far shows that the Ethicon Prolene mesh, which is made of polypropylene material, is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with it. The product becomes infected via bacterial contamination and cause chronic inflammation. Biomechanical issues that result include shrinkage, contacting, and deforming of the mesh.

33. At all times relevant hereto, the Defendant knew of the defective nature of its product and its labeling as herein set forth, yet continued to design, manufacture, market, distribute and sell its product so as to maximize sales and profits at the expense of the general public's health and safety in conscious disregard for the foreseeable harm caused by this product. Defendant's conduct exhibited such an entire want of care as to establish that its actions were a result of fraud, ill will, recklessness, gross negligence or willful and intentional disregard to the Plaintiff's individual rights, health and well-being and hence punitive damages are appropriate.

THE FDA AND HERNIA MESH RECALLS

34. The FDA has historically been quick to approve untested hernia mesh products, which benefits medical device manufacturers and hurts the public. When a product is then shown to be defective, severely injuring thousands or tens of thousands nationwide, the FDA is slow to take any action. The manufacturers of hernia mesh know of the life-threatening complications their products can cause, but they don't warn the public or surgeons.

35. There are over 100,000 hernia meshes implanted every year in the United States. Many of the most dangerous hernia meshes remain on the market and have not been recalled by the FDA. Bowel obstructions and severe infections are common complications related to hernia mesh.

36. What causes complications can vary depending on the hernia mesh product. Many hernia mesh products contain a type of plastic known as polypropylene, the same material that is used to make many types of pelvic mesh and bladder slings. The Polypropylene Material Data Safety Sheet (MSDS) notes: "Prohibited Uses: Applications involving permanent implantation into the body." However, manufacturers of these hernia products, including Defendant, continue to use polypropylene.

37. Hernia mesh frequently cause life-threating complications. Hernia mesh can erode through the bowel, requiring multiple additional surgeries, weeks of hospitalization, partial bowel removal, colostomies, and more. The mesh failure frequently causes patients to experience a systemic infection.

38. A hernia is a condition in which part of the intestine bulges through a weak area in muscles in the abdomen. An inguinal hernia occurs in the groin (the area between the abdomen and

the thigh). It's called "inguinal" because the intestines push through a weak spot in the inguinal canal, which is a triangle-shaped opening between layers of abdominal muscles near the groin. Obesity, pregnancy, heavy lifting, and straining can cause the intestine to push against the inguinal canal.

39. Although there are several techniques used by surgeons for hernia repair, physicians often favor a mesh plug. The mesh plugs have been under scrutiny for over a decade because of thousands of reports linking it with complications and devastating injuries. The plugs have shown a consistent propensity to shrink, detach, and migrate to other parts of the body where they can damage organs and nerves.

40. The hernia mesh manufactured by the Defendants are both made of woven polypropylene, which is a cheap plastic that degrades and erodes through tissue once implanted. The woven design of the mesh creates small pores or holes throughout the mesh. Nerves grow into these pores and attach to the mesh soon after the implant. As the mesh erodes and moved through the inguinal canal, it pulls and stretches the nerves attached to it. The nerves stretching is what causes the debilitating pain. Additionally, pain caused from nerves stretching is essentially untreatable. Opioids are not effective at treating nerve pain. Once the mesh has eroded into the spermatic cord, it becomes impossible to remove without also removing the testicle. This was precisely the case with the Plaintiff.

41. The scientific evidence shows that the polypropylene material from which the product is made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the products, including Plaintiff. The product can become infected via bacterial contamination and cause chronic inflammation. Biomechanical issues that result include shrinkage, contracting, creeping, and deforming of the mesh. The Defendants should have known that, yet they continued to promote the product as safe and effective, even as no long-term trials had been conducted to assure safety and efficacy.

42. Because of years of the manufacturer and implementation and insertion of these mesh products manufactured by the J&J Defendants, thousands of Plaintiffs have come forward to sue the J&J Defendants. Men have been shown to be ten times more likely than women to experience an inguinal hernia. Most men have reported severe, chronic groin and leg pain after being implanted.

Many have also lost one or both of their testicles, as has the Plaintiff.

43. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, Defendant's mesh products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re- operations, and have caused severe and irreversible injuries, conditions and damage to Plaintiff.

44. Because of their numerous defects, the mesh products create an unreasonable risk of injury and other adverse health consequences for patients, including, but not necessarily limited to, mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pelvic pain, prolapse of organs, and in most cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis and spine.

45. Defendants made, participated in, and/or contributed to filing with the Food and Drug Administration in conjunction with the clearance process and other filing requirements for Defendants' products.

46. Upon information and belief, Defendants were in control or designing, assembling, manufacturing, marketing, testing, distributing, packaging, labeling, processing, supplying, marketing, advertising, promoting, selling, and issuing of product warnings and related information with respect to its mesh products.

47. Defendants have consistently underreported and withheld information about the propensity of its mesh products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients and the public at large.

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CAUSES OF ACTION

FIRST CAUSES OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against all Defendants)

48. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

49. Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling directly and indirectly through third parties or related entities the J&J Prolene Mesh.

50. Defendants had a duty to place into the stream of commerce, manufacture, distribute, design, test, promote and sell the J&J Prolene Mesh so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

51. The J&J Prolene Mesh that was surgically implanted into Plaintiff was defective and unreasonably dangerous.

52. At all times material to this action, the J&J Prolene Mesh was expected to reach, and did reach, consumers and healthcare providers in the State of California and throughout the United States, including Plaintiff and Plaintiff's healthcare providers, without substantial change in the condition in which it was sold. At the time the J&J Prolene Mesh left the possession of Defendants, and the time the J&J Prolene Mesh entered the stream of commerce, the J&J Prolene Mesh was in an unreasonably dangerous and defective condition. These defects, include, but are not limited to, the following:

a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.

b. The mesh material harbors infections that adversely affect human tissues and patient health.

c. The mesh products migrate from the location of their implantation, adversely affecting tissues and patient health.

d. If polypropylene, the mesh material abrades tissues adversely affecting patient health.

e. The pelvic mesh products regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.

f. Due to their various defects, the pelvic mesh products regularly cause significant injury to patients such that the mesh products must be removed, resulting in additional surgery.

g. The mesh products become embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to the organs and tissues, adversely affecting patient health.

h. The mesh products are defective in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered.

i. The mesh products erode into other pelvic organs, tissue, muscle, nerves, and bone adversely affecting tissues and patient health.

j. The Defendants designed and defected an unreasonable dangerous hernia mesh product.

k. Failed to adequately research the mesh. The Defendants knew or should have known about the potential risk of infections, allergic reactions, bowel damage and other internal injuries but withheld his information from patients and doctors.

l. Defendants failed to properly investigate reports of problems after the hernia mesh was introduced.

m. Defendants failed to warn about the risk of injury.

n. Defendants failed to promptly issue a recall after the problems were discovered.

53. Plaintiff used the J&J Prolene Mesh for its intended purpose.

54. Plaintiff could not have discovered any defect in the J&J Prolene Mesh through the exercise of due care.

55. Defendants as designer, manufacturer, marketer, and distributor of the ASR Hip Implant Device, are held to the level of knowledge of an expert in its field.

56. Neither Plaintiff nor Plaintiff's healthcare providers had substantially the same knowledge as the Defendants.

57. As a direct and proximate result of the defective manufacturing and the unreasonably dangerous and defective characteristics of the J&J Prolene Mesh and the Defendants' failure to comply with federal standards and requirements, Plaintiff suffered severe and permanent injuries. Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiff suffered severe pecuniary loss. Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

58. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against all Defendants)

59. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

60. The J&J Prolene Mesh implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. The Product's propensity to contract, retract, and/or shrink inside the body;

b. The Product's propensity for degradation, fragmentation and/or creep;

c. The product's inelasticity preventing proper mating with tissue;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Product;

f. The risk of chronic infections resulting from the Product;

g. The risk of permanent scarring as a result of the Product;

h. The risk of recurrent hernias, intractable hernia pain and/other pain resulting from the Product;

i. The need for corrective or revision surgery to adjust or remove the Product;

j. The severity of complications that could arise as a result of the implantation of the Product;

k. The hazards associated with the Product;

l. The Product's defects described herein;

m. Treatment of hernias with the Product is no more effective than feasible available alternatives;

n. Treatment of hernias with the Product exposes patients to greater risk than feasible available alternatives;

o. Treatment of hernias with the Product makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

61. The J&J Prolene Mesh was implanted in Plaintiff and Plaintiff used the J&J Prolene Mesh for its intended purpose.

62. Plaintiff could not have discovered any defects in the J&J Prolene Mesh through the exercise of reasonable care.

63. Defendants as designer, manufacturer, marketer, and distributor of the ASR Hip Implant Device, are held to the level of knowledge of an expert in its field.

64. The warnings that were given by the Defendants were not accurate, clear, and/or were ambiguous.

65. The warnings that were given by the Defendants failed to properly warn physicians or consumers of the risk of failure of the J&J Prolene Mesh for patients.

66. Plaintiff, individually, and through Plaintiff's prescribing/treating physicians, reasonably relied on the skill, superior knowledge, and judgment of the Defendants.

67. Had Plaintiff received adequate warnings regarding the risks of the subject products, Plaintiff would not have used it.

68. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of the J&J Prolene Mesh and the Defendants' failure to comply with federal standards and requirements, Plaintiff suffered severe and permanent injuries. Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiff suffered severe pecuniary loss. Plaintiff seek actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

69. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against All Defendants)

70. Plaintiff hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

71. Defendants designed, manufactured, tested, marketed, distributed, and sold into the stream of commerce the J&J Prolene Mesh.

72. The J&J Prolene Mesh that was surgically implanted in Plaintiff was defective in its design when it left the hands of Defendants, in that the design was flawed thereby posing a serious risk to Plaintiff. The Product's design defects include, but are not limited to:

a. The use of polypropylene material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn causes surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. Adverse reactions to the mesh, adhesions, injuries to nearby organs, nerves or blood vessels, and complications including infection, chronic pain and hernia recurrence;

e. The propensity of the Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Product, causing it to be improperly mated to the areas where implanted, and causing pain upon normal daily activities; and

g. The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time.

73. As a direct and proximate result of the defective and inappropriate design and the

unreasonably dangerous and defective characteristics of the J&J Prolene Mesh and the Defendants' failure to comply with federal standards and requirements, Plaintiff suffered severe and permanent injuries. Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiff suffered severe pecuniary loss. Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

74. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(Against All Defendants)

75. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

76. Prior to the time that the J&J Prolene Mesh Implant Device was used by Plaintiff, Defendants impliedly warranted to Plaintiff and her physicians that the J&J Prolene Mesh Implant Device was of merchantable quality and safe and fit for the use for which it was intended.

77. Plaintiff and Plaintiff's healthcare providers and her physicians were and are unskilled in the research, design and manufacture of the J&J Prolene Mesh Implant Device, and they reasonably relied entirely on the skill, judgment and implied warranty of Defendants in using the J&J Prolene Mesh.

78. The J&J Prolene Mesh was neither safe for its intended use nor of merchantable

quality, as warranted by Defendants, in that it had dangerous propensities when put to its intended use, causing severe injuries to the user.

79. Defendants, by selling, delivering and/or distributing the defective J&J Prolene Mesh to Plaintiff breached the implied warranty of merchantability and fitness and caused Plaintiff to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

80. As a result of the aforementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against All Defendants)

81. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

82. At all times herein mentioned, Defendants expressly warranted to Plaintiff and Plaintiff's healthcare providers, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned J&J Prolene Mesh was safe, effective, fit and proper for its intended use.

83. In utilizing the aforementioned J&J Prolene Mesh, Plaintiff and her healthcare providers relied on the skill, judgment, representations and foregoing express warranties of Defendants.

84. Said warranties and representations were false in that the aforementioned J&J Prolene Mesh was not safe and was unfit for the uses for which it was intended.

85. As a result of the foregoing breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

86. Plaintiff hereby incorporate by reference, as if fully set forth herein, each and every

allegation set forth in the preceding paragraphs and further alleges as follows:

87. Defendants had a duty to individuals, including Plaintiff to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the J&J Prolene Mesh.

88. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the J&J Prolene Mesh. Defendants breached their aforementioned duty by:

a. Failing to design the Product so as to avoid an unreasonable risk of harm to person in whom the Product was implanted, including Plaintiff;

b. Failing to manufacture the Product so as to avoid an unreasonable risk of harm to persons in whom the Product was implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Product so as to avoid an unreasonable risk of harm to person in whom the Product was implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Product so as to avoid an unreasonable risk of harm to person in whom the Product was implanted, including Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the product;

89. The reasons that Defendants' negligence caused the Product to be unreasonably dangerous and defective include, but are not limited to:

a. The use of polypropylene material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn causes surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. Adverse reactions to the mesh, adhesions, injuries to nearby organs, nerves or blood vessels, and complications including infection, chronic pain and hernia recurrence;

e. The propensity of the Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Product, causing it to be improperly mated to the areas where implanted, and causing pain upon normal daily activities; and

g. The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time.

90. Defendants also negligently failed to warn or instruct Plaintiff and/or her healthcare providers, of subjects, including but not limited to the following:

a. The Product's propensity to contract, retract, and/or shrink inside the body;

b. The Product's propensity for degradation, fragmentation and/or creep;

c. The product's inelasticity preventing proper mating with tissue;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Product;

f. The risk of chronic infections resulting from the Product;

g. The risk of permanent scarring as a result of the Product;

h. The risk of recurrent hernias, intractable hernia pain and/other pain resulting from the Product;

i. The need for corrective or revision surgery to adjust or remove the Product;

j. The severity of complications that could arise as a result of the implantation of the Product;

k. The hazards associated with the Product;

l. The Product's defects described herein;

m. Treatment of hernias with the Product is no more effective than feasible available alternatives;

n. Treatment of hernias with the Product exposes patients to greater risk than feasible available alternatives;

o. Treatment of hernias with the Product makes future surgical repair more

difficult than feasible available alternatives;

p. Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

91. As a direct and proximate result of the defective and inappropriate design and the unreasonably dangerous and defective characteristics of the J&J Prolene Mesh and the Defendants' failure to comply with federal standards and requirements, Plaintiff suffered severe and permanent injuries. Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiff suffered severe pecuniary loss. Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

92. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION

VIOLATION OF BUSINESS AND PROFESSIONS CODE §17200

(Against All Defendants)

93. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

94. Plaintiff brings this cause of action pursuant to California Business & Professions Code §17204, in Plaintiff's individual capacity, and not on behalf of the general public.

95. California Business & Professions Code §17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

96. The acts and practices described above were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of California Business & Professions Code §17200. The acts of untrue and misleading advertising are, by definition, violations of California Business & Professions Code §17200. This conduct includes, but is not limited to:

a. Representing to Plaintiff, Plaintiff's healthcare providers and the general public that the J&J Prolene Mesh was safe, fit, and effective for human use, knowing that said representations were false, and concealing from Plaintiff, Plaintiff's healthcare providers, and the general public that the J&J Prolene Mesh had a propensity to cause serious injuries to Plaintiff;

b. Failing to disclose that the J&J Prolene Mesh could cause serious injuries and thereby give rise to unnecessary pain and suffering, debilitation, and the need for additional surgeries to replace the Product with attendant risks of further surgery, such as complications and death; and

c. Purposely downplaying and understating the risks associated with the J&J Prolene Mesh.

97. These practices constitute unlawful, unfair and fraudulent business acts or practices, within the meaning of California Business & Professions Code §17200, as well as unfair, deceptive, untrue and misleading advertising as prohibited by California Business & Professions Code §17200.

98. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of ill-gotten gains from the sale of the J&J Prolene Mesh in California, sold in large part as a result of the acts and omissions described herein.

99. Because of fraudulent misrepresentations made by Defendants as detailed above, and the inherently unfair practice of committing a fraud against the public by intentionally misrepresenting and concealing material information, the acts of Defendants described herein constitute unfair or fraudulent business practices.

100. Plaintiff, pursuant to California Business & Professions Code §17200, seeks an order of this Court compelling the Defendants to provide restitution and injunctive relief calling for Defendants, and each of them, to cease unfair business practices in the future.

EIGHTH CAUSE OF ACTION

VIOLATION OF BUSINESS AND PROFESSIONS CODE §17500

(Against All Defendants)

101. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

102. Plaintiff brings this cause of action pursuant to California Business & Professions Code §17500, in Plaintiff's individual capacity and not on behalf of the general public.

103. California Business & Professions Code §17500 provides that it is unlawful for any person, firm, corporation or association to dispose of property or perform services, or to induce the public to enter into any obligation relating thereto, through the use of untrue or misleading statements.

104. At all times herein alleged Defendants have committed acts of disseminating untrue and misleading statements as defined by California Business & Professions Code §17500 by engaging in the following acts and practices with intent to induce members of the public, including healthcare professionals, to purchase and use the J&J Prolene Mesh. This conduct includes, but is not limited to:

a. Representing to Plaintiff, Plaintiff's healthcare providers and the general public that the J&J Prolene Mesh was safe, fit, and effective for human use, knowing that said representations were false, and concealing from Plaintiff, Plaintiff's healthcare providers, and the general public that the J&J Prolene Mesh had a propensity to cause serious injuries to Plaintiff;

b. Failing to disclose that the J&J Prolene Mesh could cause serious injuries and thereby give rise to unnecessary pain and suffering, debilitation, and the need for additional surgeries to replace the Product with attendant risks of further surgery, such as complications and death; and

c. Purposely downplaying and understating the risks associated with the J&J Prolene Mesh.

105. The foregoing practices constitute false and misleading advertising within the meaning

of California Business & Professions Code §17500.

106. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of ill-gotten gains from the sale of the J&J Prolene Mesh in California, sold in large part as a result of the acts and omissions described herein.

107. Pursuant to California Business & Professions Code §17535, Plaintiff seeks an order of this Court compelling the Defendants to provide restitution and injunctive relief calling for Defendants, and each of them, to cease unfair business practices in the future.

108. Plaintiff seeks restitution of the monies collected by Defendants, and each of them, injunctive relief to cease such false and misleading advertising in the future, attorney's and costs, punitive damages, and compensatory damages.

NINTH CAUSE OF ACTION

VIOLATION OF CIVIL CODE §1750

(Against All Defendants)

109. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

110. Plaintiff brings this cause of action pursuant to California Business & Professions Code §17204, in Plaintiff's individual capacities, and not on behalf of the general public.

111. Plaintiff is informed and believes and thereon alleges that Defendants, and each of them, by the acts and misconduct alleged herein, violated Consumers Legal Remedies Act, California Civil Code §§1750 et. seq. ("CLRA").

112. Plaintiff hereby seeks injunctive relief as appropriate against Defendants, and each of them, for their violations of California Business & Professions Code §1750 et. seq. The CLRA applies to Defendants' actions and conduct described herein because it extends to transactions which are intended to result, or which have resulted, in the sale of goods to consumers.

113. Plaintiff is a "consumer" within the meaning of California Civil Code §1761(d).

114. Defendants have violated, and continue to violate, the CLRA in representing that goods have characteristics and benefits which they do not have in violation of California Civil Code

§1771(a)(5).

115. At all times herein alleged Defendants have committed acts of disseminating untrue and misleading statements as defined by California Civil Code §1770 by engaging in the following acts and practices with intent to induce members of the public, including healthcare providers, to purchase and use the J&J Prolene Mesh but is not limited to:

a. Representing to Plaintiff, Plaintiff's physicians, and the general public that the J&J Prolene Mesh was safe, fit, and effective for human use, knowing that said representations were false, and concealing from Plaintiff, Plaintiff's physicians, and the general public that the J&J Prolene Mesh had a propensity to cause serious injuries to users, including an unacceptably high failure rate; and

b. Purposely downplaying and understating the risks associated with the J&J Prolene Mesh.

116. The foregoing practices constitute false and misleading advertising and representations within the meaning of California Civil Code §1770.

117. Pursuant to California Civil Code §1780, Plaintiff seeks an order of this court for injunctive relief calling for Defendants, and each of them, to cease such deceptive business practices in the future.

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

118. Plaintiff incorporates by reference the factual portion of this petition as if fully set forth herein and additionally or in the alternative, if same be necessary, alleges as follows:

119. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortuous nature of wrongdoing that causes the injury.

120. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the J&J Prolene Mesh were not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

121. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injuries and the connection between the injuries and Defendants tortious conduct.

PRAYER FOR RELIEF

THEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

1. Awarding past and future medical and incidental expenses, according to proof;
2. Awarding past and future loss of earnings and/or earning capacity, according to proof;
3. Awarding past and future general damages, according to proof;
4. Awarding punitive and/or treble damages to Plaintiff;
5. Awarding prejudgment and post judgment interest;
6. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law;
7. Awarding the costs and expenses of this litigation to Plaintiff;
8. Granting the injunctive relief requested above; and
9. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

Dated: September 30, 2017

Respectfully submitted,

By */s/ Richard Salkow*

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